

## REMARKS

The election/restriction requirement dated August 2, 2006, has been considered. The Examiner contends that the claims are drawn to four inventions, namely Group I (Claims 1-26), Group II (Claims 27-43 and 50-52), Group III (Claims 44-49), and Group IV (Claims 53-60) and asserts that restriction to one of claim Groups I-IV is required under 35 U.S.C. §121. The claims of **Group I (Claims 1-26)** are provisionally elected *with traverse*. Applicant traverses the restriction requirement as it fails to satisfy the requirements for maintaining such a restriction requirement and accordingly requests reconsideration and withdrawal of the restriction requirement.

The Examiner has presented several reasons for restricting the various identified groups. To summarize, the groups directed to methods (I and IV) have been restricted from each other and the groups directed to apparatuses (II and III) have been restricted from each other, each of which is based on MPEP §806.05(c) as being a combination and subcombination. Further, both of the method groups (Groups I and IV) have been restricted with respect to each of the apparatus groups (Groups II and III) on the basis of MPEP §806.05(e) as being processes and apparatuses for practicing them. Each of these bases for restriction is traversed and discussed below.

### Combination and Subcombination Restrictions

In paragraph 4 of the restriction requirement, the Examiner contends that the claims of Groups IV and I are related as combination and subcombination, which is governed by MPEP §806.05(c). MPEP §806.05(c) requires, among other things, that the Examiner establish two prongs of distinctness which involve establishing the following:

- 1) the “combination” does not require the particulars of the subcombination as claimed for patentability, and
- 2) the “subcombination” has utility either by itself or in another materially different combination.

With respect to the first prong, Applicant respectfully submits that the asserted restriction violates the specific rule set forth in MPEP §806.05(c)(I). This section states:

Where a combination *as claimed* sets forth the details of the subcombination *as separately claimed*, there is no evidence that combination AB<sup>sp</sup> is patentable without the details of B<sup>sp</sup>. The inventions are not distinct and a requirement for restriction must not be made or maintained, even if the subcombination has separate utility. This situation can be diagrammed as combination AB<sup>sp</sup> (“sp” is an abbreviation for “specific”), and subcombination B<sup>sp</sup>. Thus the specific characteristics required by the subcombination claim B<sup>sp</sup> are also required by the combination claim. (*emphasis in original*)

Claim 53 (Group IV) is directed to selecting one or more surface electrode locations and determining one or more subcutaneous electrode implant locations, where such limitations are also set forth in independent Claim 18 (Group I). The asserted combination *as claimed* in Claim 53 sets forth the asserted subcombination *as separately claimed* in Claim 18; therefore, “[t]he inventions are not distinct and a requirement for restriction must not be made or maintained....” Further, the Examiner’s reasoning for requiring restriction of Groups I and IV is factually erroneous. Contrary to the Examiner’s assertion that the combination (as set forth in Claim 53) is merely directed to first and second surface electrodes, Applicant notes that Claim 53 recites “providing at least a pair of surface electrodes” (*emphasis added*). The claims of both Groups I and IV are not limited as to the number of electrodes that may be used, and the identified combination at least includes the particulars of the identified subcombination. Thus, the restriction of Groups I and IV is improper as the Examiner has not satisfied each of the requirements for maintaining a restriction based on MPEP §806.05(c), and the restriction would directly violate the requirements set forth in the MPEP. Applicant accordingly requests that the restriction requirement be withdrawn.

In paragraph 5, the Examiner contends that the claims of Groups II and III are related as combination and subcombination, which is governed by MPEP §806.05(c). While the Examiner must show that both prongs of the above-discussed test are met, Applicant submits that at least the first prong has not been satisfied. The Examiner asserts that the combination does not require the particulars of the subcombination because the subcombination has means for only rejecting locations whereas the combination cannot merely reject locations since it must determine acceptable locations. However, Claim 44 (Group III) includes “means for selecting or rejecting,” which indicates that the “means” is capable of both selecting and

rejecting locations. Thus, the claims of both Groups II and III are directed to determining acceptable locations including selecting or rejecting locations, and the identified combination at least includes the particulars of the identified subcombination. Thus, the restriction of Groups II and III is improper as the Examiner has not satisfied each of the requirements for maintaining a restriction based on MPEP §806.05(c). Applicant accordingly requests that the restriction requirement be withdrawn.

#### Process and Apparatus for Practice

In paragraphs 2 and 6, the Examiner asserts that the claims of Groups I and II, and IV and II, respectively, are related as process (Groups I and IV) and apparatus for its practice (Group II). In order to maintain a restriction based on such an assertion, MPEP §806.05(e) indicates that the Examiner must show that either the process as claimed can be practiced by another materially different apparatus or that the apparatus as claimed can be used to practice another materially different process. The Examiner's assertion that the apparatus of Group II can be used to deliver pacing pulses to a patient which is not explicitly required in the processes of Group I or IV is incorrect and insufficient to support the asserted restriction.

Contrary to the Examiner's assertion, the processes as claimed in both Groups I and IV require that pacing pulses be delivered to a patient. Claim 1 (Group I) and Claim 53 (Group IV) recite limitations directed to determining a surface pacing level (or threshold) using at least two surface electrodes. The Specification clearly indicates, and one skilled in the art would recognize, that determining a surface pacing level includes delivering pacing pulses to a patient, as pacing must take place to determine the pacing level. *See, e.g.*, page 31, lines 14-28. Thus, the asserted materially different process (delivering pacing pulses to a patient) is not materially different as it is included in the processes, as claimed, of Groups I and IV. Further, the Examiner's assertion that delivering pacing pulses to a patient is not explicitly required is not relevant. The MPEP does not require that the limitations of the apparatus claims be explicitly recited in the process claims. As the process claims of Groups I and IV include the asserted "materially different" process, the requisite evidence for requiring restriction under MPEP §806.05(e) has not been shown, and the restriction of the

claims of Groups I and IV from those of Group II is improper. Applicant accordingly requests that the restriction requirement be withdrawn.

In paragraph 3, the Examiner asserts that the claims of Groups I and III are related as process (Group I) and apparatus for its practice (Group III). The Examiner's assertion that the process of Group I does not require that the electrodes be placed relative to a patient's heart which is required by the apparatus of Group III is erroneous and insufficient to support the asserted restriction. Contrary to the Examiner's assertion, the claims of both Groups I and III include limitations directed to locating or placing surface electrodes on a thorax of a patient. *See, e.g.*, Claim 1 (Group I) and Claim 44 (Group III). The Examiner has not shown that placing surface electrodes on a patient's thorax is materially different than placing surface electrodes on a patient's thorax "relative to a patient's heart." Moreover, the Specification clearly indicates, and one skilled in the art would recognize, that locating surface electrodes on a thorax of a patient would include placement relative to the patient's heart. *See, e.g.*, page 35, lines 5-22.

The Examiner has not shown, or asserted, that either the process as claimed can be practiced by another materially different apparatus or that the apparatus as claimed can be used to practice another materially different process. Applicant notes that MPEP §806.05(e) indicates that it is the Examiner's burden to provide a reasonable example that recites a material difference. Since a materially different apparatus has not been identified and placing surface electrodes on a patient's thorax has not been shown to be materially different from placing surface electrodes on a patient's thorax relative to a patient's heart, the requisite evidence for requiring restriction under MPEP §806.05(e) has not been shown. Thus, the restriction of the claims of Group I from those of Group III is improper. Applicant accordingly requests that the restriction requirement be withdrawn.

In paragraph 7, the Examiner asserts that the claims of Groups IV and III are related as process (Group IV) and apparatus for its practice (Group III). The Examiner's assertion that the apparatus of Group III can be carried out without using a support structure supporting two electrodes as required by the process of Group IV is insufficient to support the asserted restriction. The Examiner has not shown, or asserted, that either the process as claimed can

be practiced by another materially different apparatus or that the apparatus as claimed can be used to practice another materially different process. Applicant notes that MPEP §806.05(e) indicates that it is the Examiner's burden to provide a reasonable example that recites a material difference.

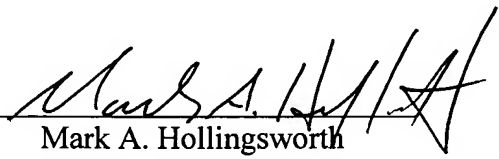
In an effort to facilitate prosecution, and without limiting the scope of the claims, Applicant has amended Claim 44 (Group III) to include "means for positioning a plurality of surface electrodes." Thus, the claims of Group III are now clearly directed to an apparatus that can include a supporting structure as included in the claims of Group IV. Support for these changes may be found, for example, in Figs. 5A-B and Claim 53, and therefore do not introduce new matter. Since a materially different apparatus has not been identified and the apparatus claims of Group III include structure for performing the process, as claimed, in the claims of Group IV, the requisite evidence for requiring restriction under MPEP §806.05(e) has not been shown. Thus, the restriction of the claims of Group IV from those of Group III is improper. Applicant accordingly requests that the restriction requirement be withdrawn.

For at least these reasons, Applicant submits that the Examiner has not presented the evidence required to satisfy the burden of maintaining the restriction requirement. Without such evidence, the restriction requirement is improper. Accordingly, Applicant requests that the restriction requirement to alleged inventions I, II, III and IV be reconsidered and withdrawn. If the Examiner would find it helpful to discuss this issue by telephone, the undersigned attorney of record invites the Examiner to contact the attorney of record.

Respectfully submitted,

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